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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,016	LULLA ET AL.	
	Examiner	Art Unit	
	KRISTIE L. BROOKS	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-22, 25-42, and 44-45*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *23,24,43 and 46-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,25-42,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/5/05; 7/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-22, and 25-45 are drawn to a pharmaceutical formulation comprising azelastine and a steroid, classified in class 514, subclass 171.

   II. Claims 23-24 are drawn to drawn to a pressure packing, classified in class 128, subclass 200.23.

   III. Claims 46-50 are drawn to a method of use, classified in class 514, subclass 171.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed do not overlap in scope because the two inventions have materially different design and mode of operation. Invention II is drawn to a pressure packing device or metered dose inhaler where a composition is delivered by spray or aerosol which is different from the pharmaceutical formulation of Invention I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product of invention I can be used in a materially different process, such as, improving vision .

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process of Invention III, can be used with a materially different product, such as, without the pressure packing device or metered dose inhaler of Invention II.

2. For purpose of examination, the Examiner has requested Applicant to provisionally elect a single steroid selected from: beclomethasone, mometasone, fluticasone, or a pharmaceutically acceptable ester thereof, budesonide or cyclosenide.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement

will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Telephone Election

5. During a telephone conversation with Attorney Tom Pavelko on May 21, 2008 a provisional election was made without traverse to prosecute Invention I, claims 1-22 and 25-45. A provisional election of species of fluticasone was also made.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-24, 32-34, 39-42 and 46-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Status of Application

6. Claims 1-50 are pending.

7. Claims 23-24, 32-34, 39-42 and 46-50 are withdrawn from further consideration as being drawn to the non-elected invention.

Claim Objections

8. Claims 5-22 and 45 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 6, 18 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). **In the present instance, claim 6** recites the broad recitation "wherein the formulation particle size of less than 10 μm", and the claim also recites phrases "preferably less than 5 μm", which is the narrower statement of the range/limitation.

Claim 18 recites "...wherein the buffer maintains a pH of the aqueous phase at from 3 to 7...", and the claim also recites phrases "preferably 4.5 to about 6", which is the narrower statement of the range/limitation.

Claim 18 is also indefinite due to the phrase "less than about 10μm," which simultaneously refers to a broad range and a narrower range. For example, in claim 2, the conflicting phrase "less than about 10μm " is unclear as to whether it is less than 10μm, in which the range cannot be greater than 10μm, or about 10μm thereof, in which the range can include a value above 10μm. Therefore, it would be unclear to a skilled artisan, which range Applicant has intended.

For purposes of examination, the Examiner has interpreted "less than about 10μm thereof" to mean less than 10μm.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language.

The claim refers to formulations described in the Examples of the specification. It is unclear what is encompassed by the claim and what is included in the formulations. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4, 7,9-10,12-21, 30-32, and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Cramer (EP 0780127).

Cramer teaches a nasal spray composition comprising about 0.001 to about 0.2% concentration of a glucocorticosteroid (i.e. beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, bedusonide and pharmaceutically acceptable salts), 0.01 to about 4% concentration of an antihistamine (i.e. azelastine or pharmaceutically acceptable salt thereof), and an intranasal carrier (see the abstract and page 2 lines 36-45). The composition may contain isotonic agents such as citric acid, boric acid, propylene glycol, etc., thickening agents such as xanthan gum, microcrystalline cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, etc., humectants such as sorbitol, propylene glycol, polyethylene glycol, etc. and preservatives such as benzyl alcohol, phenylethyl alcohol, and quaternary ammoniums such as benzalkonium chloride (see page 4 lines 50-58 and page 5 lines 1-22). The pH

of the composition is from about 4.5 to about 9 (see page 2 lines 57-58). The composition may be formulated into a nasal solution (for use as drops or a spray), a nasal suspension, ointment, or gel (see page 3 lines 43-47). Typically the dosage units may be prepared to deliver 0.5mcg to about 100mcg of the glucocorticoid and 5mcg to about 1000mcg of the antihistamine spray (see page 3 lines 58 and page 4 lines 1-2). Example III discloses an intranasal pharmaceutical composition prepared by combining the following components utilizing conventional mixing techniques, shown below:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.075
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

(see page 6, Example III).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 5, 35-38 and 43 are rejected under U.S.C. 103(a) as being unpatentable over Cramer (EP 0780127).

Applicant claims a pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and a steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, preferably the formulation being in a form suitable for nasal or ocular administration.

Determination of the scope and content of the prior art (MPEP 2141.01)

Cramer teaches a nasal spray composition comprising about 0.001 to about 0.2% concentration of a glucocorticosteroid (i.e. beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, bedusonide and pharmaceutically acceptable salts), 0.01 to about 4% concentration of an antihistamine (i.e. azelastine or pharmaceutically acceptable salt thereof, and an intranasal carrier (see the abstract and page 2 lines 36-45). The composition may contain isotonic agents such as citric acid, boric acid, propylene glycol, etc., thickening agents such as xanthan gum, microcrystalline cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, etc.,

humectants such as sorbitol, propylene glycol, polyethylene glycol, etc. and preservatives such as benzyl alcohol, phenylethyl alcohol, and quaternary ammoniums such as benzalkonium chloride (see page 4 lines 50-58 and page 5 lines 1-22). The pH of the composition is from about 4.5 to about 9 (see page 2 lines 57-58). The composition may be formulated into a nasal solution (for use as drops or a spray), a nasal suspension, ointment, or gel (see page 3 lines 43-47). Typically the dosage units may be prepared to deliver 0.5mcg to about 100mcg of the glucocorticoid and 5mcg to about 1000mcg of the antihistamine spray (see page 3 lines 58 and page 4 lines 1-2). Example III discloses an intranasal pharmaceutical composition prepared by combining the following components utilizing conventional mixing techniques, shown below:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

(see page 6, Example III).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Cramer does not exemplify a composition comprising azelastine and fluticasone.

Finding of prima facie obviousness Rational and Motivation (MPEP 2142-2143)

However, one of ordinary skill in the art would have been motivated to make a composition comprising azelastine and fluticasone because Cramer suggests that the combination of a glucocorticoid (i.e. fluticasone) and antihistamine (i.e. azelastine) provide improved relief of symptoms associated with seasonal or perennial allergic rhinoconjunctivitis.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a composition comprising azelastine and fluticasone for the purpose of providing intranasal compositions with improves effectiveness in the treatment of seasonal or perennial allergic rhinoconjunctivitis.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

15. Claims 22 and 26-27 are rejected under U.S.C. 103(a) as being unpatentable over Cramer (EP 0780127) in view of Modi (US 6,294,153).

Applicant claims a pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and a steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, preferably the formulation being in a form suitable for nasal or ocular administration.

Determination of the scope and content of the prior art (MPEP 2141.01)

Cramer teaches a nasal spray composition comprising about 0.001 to about 0.2% concentration of a glucocorticosteroid (i.e. beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, bedusonide and pharmaceutically acceptable salts), 0.01 to about 4% concentration of an antihistamine (i.e. azelastine or pharmaceutically acceptable salt thereof, and an intranasal carrier (see the abstract and page 2 lines 36-45). The composition may contain isotonic agents such as citric acid, boric acid, propylene glycol, etc., thickening agents such as xanthan gum, microcrystalline cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, etc., humectants such as sorbitol, propylene glycol, polyethylene glycol, etc. and preservatives such as benzyl alcohol, phenylethyl alcohol, and quaternary ammoniums such as benzalkonium chloride (see page 4 lines 50-58 and page 5 lines 1-22). The pH of the composition is from about 4.5 to about 9 (see page 2 lines 57-58). The composition may be formulated into a nasal solution (for use as drops or a spray), a nasal suspension, ointment, or gel (see page 3 lines 43-47). Typically the dosage units may be prepared to deliver 0.5mcg to about 100mcg of the glucocorticoid and 5mcg to about 1000mcg of the antihistamine spray (see page 3 lines 58 and page 4 lines 1-2). Example III discloses an intranasal pharmaceutical composition prepared by combining the following components utilizing conventional mixing techniques, shown below:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

(see page 6, Example III).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Cramer does not exemplify a nasal composition further comprising a propellant. This deficiency is cured by the teachings of Modi.

Modi teaches aerosol formulations for nasal delivery comprising pharmaceutical agents (i.e. anti-inflammatories, steroids, etc.), water, excipients and a propellant (see the abstract and column 3 lines 30-40). Improved penetration and absorption of the formulations can be achieved by mixing the formulation with propellants such as tetrafluroethane, etc., especially when delivered through aerosol devices (i.e. MDI). (see column 2 lines 5-24).

Finding of prima facie obviousness Rational and Motivation (MPEP 2142-2143)

One of ordinary skill in the art would have been motivated to make a composition further comprising a propellant because Modi suggests that adding propellants to nasal formulations can increase penetration and absorption in the nasal cavity.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a composition further comprising a propellant for the purpose of increasing penetration of active formulations into the nasal cavity.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

16. Claims 1-3 and 6 are rejected under U.S.C. 103(a) as being unpatentable over Malmqvist-Granlund et al. (US 6,391,340).

Applicant claims a pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and a steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, preferably the formulation being in a form suitable for nasal or ocular administration.

Determination of the scope and content of the prior art (MPEP 2141.01)

Malmqvist-Granlund et al. teach a dry powder solid particulate pharmaceutical formulation suitable for application to the nose comprising finely divided drug particles and a carrier, where at least 70% of the drug particles have a size below 15µm (see the abstract and column 1 lines 52-62). The drugs that are used are classes of drugs used to treat conditions of the nose such as antihistamines (i.e. azelastine) and anti-inflammatories (i.e. fluticasone) and mixtures thereof (see column 2 lines 36-40). Salts, hydrates, solvates and esters of the drugs can also be used (see column 2 lines 36-42).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Malmqvist-Granlund et al. do not exemplify a dry powder composition comprising azelastine and a steroid with a particle size of less than 10µm.

Finding of prima facie obviousness Rational and Motivation (MPEP 2142-2143)

However, one of ordinary skill in the art would have been motivated to make a composition comprising azelastine and a steroid because Malmqvist-Granlund et al. suggest a dry powder formulation with a particle size of less than 15µm comprising a anti-inflammatory (i.e. fluticasone) and a antihistamine (i.e. azelastine), which will disperse evenly over the nasal mucosa.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a composition comprising azelastine and a steroid

for the purpose of obtaining the benefits for the nose from such a combination and for increased delivery to the nasal mucosa.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

17. Claims 28-29 are rejected under U.S.C. 103(a) as being unpatentable over Cramer (EP 0780127) in view of Alfonso et al. (US 6,017,963).

Applicant claims a pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and a steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, preferably the formulation being in a form suitable for nasal or ocular administration.

Determination of the scope and content of the prior art (MPEP 2141.01)

Cramer teaches a nasal spray composition comprising about 0.001 to about 0.2% concentration of a glucocorticosteroid (i.e. beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, bedusonide and pharmaceutically acceptable salts), 0.01 to about 4% concentration of an antihistamine (i.e. azelastine or pharmaceutically acceptable salt thereof, and an intranasal carrier (see the abstract and

page 2 lines 36-45). The composition may contain isotonic agents such as citric acid, boric acid, propylene glycol, etc., thickening agents such as xanthan gum, microcrystalline cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, etc., humectants such as sorbitol, propylene glycol, polyethylene glycol, etc. and preservatives such as benzyl alcohol, phenylethyl alcohol, and quaternary ammoniums such as benzalkonium chloride (see page 4 lines 50-58 and page 5 lines 1-22). The pH of the composition is from about 4.5 to about 9 (see page 2 lines 57-58). The composition may be formulated into a nasal solution (for use as drops or a spray), a nasal suspension, ointment, or gel (see page 3 lines 43-47). Typically the dosage units may be prepared to deliver 0.5mcg to about 100mcg of the glucocorticoid and 5mcg to about 1000mcg of the antihistamine spray (see page 3 lines 58 and page 4 lines 1-2). Example III discloses an intranasal pharmaceutical composition prepared by combining the following components utilizing conventional mixing techniques, shown below:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

(see page 6, Example III).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Cramer does not exemplify a nasal composition further comprising a propellant. This deficiency is cured by the teachings of Alfonso et al.

Alfonso et al. teaches intranasal and/or inhalation administration of pharmaceutical agents (see the abstract). The dosage form suitable for intranasal and/or inhalation administration can be in the form of a liquid solution suspension, insufflation powder, etc. for administration as a nasal spray, drop or inhaled fine particles (i.e. insuflation) (see column 3 lines 1-65, column 5 lines 36-45, and column 7 lines 1-26).

Finding of prima facie obviousness Rational and Motivation (MPEP 2142-2143)

One of ordinary skill in the art would have been motivated to make the instant composition in the form of an insufflation powder because Alfonso et al. suggest the nasal compositions in the form of a spray, droplet, insufflation powder, etc.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the instant composition in the form of an insufflation powder because it is an obvious variation of ways to administer a nasal composition as suggested Alfonso et al.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

Conclusion

18. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIE L. BROOKS whose telephone number is (571)272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB

/Mina Haghighatian/
Primary Examiner, Art Unit 1616